

## REMARKS

The Examiner has rejected Claims 1 through 14. Claim 1 has been amended to clarify that the claimed subject matter relates to a bone biopsy aspiration device. Claims 6, 8, and 12 have been amended to correct obvious grammatical errors. Claims 1 through 14 are pending. It is believed that no new matter has been added by way of these amendments.

### Rejections under 35 U.S.C. §102:

Claim 1 has been rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Pyles U.S. Patent No. 5,669,882. Applicant respectfully traverses this rejection for the following reasons.

The Examiner argues that Pyles discloses a number of structural features set forth in Applicant's claim 1. In order for a claim to be anticipated under 35 U.S.C. §102, a single prior art reference must disclose each and every element of the claimed invention. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984). If the reference fails to suggest even one limitation of the claimed invention, the claim is not anticipated. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 409,411 (Fed. Cir. 1984).

The Examiner has failed to present a single prior art reference that anticipates Applicant's claimed invention. Specifically, the Examiner apparently ignored the claimed subject matter to assert that the claimed invention is anticipated by Pyles. Applicant's claimed invention is a *bone marrow biopsy device and system*. Applicant has amended claim1 to clarify this point. Pyles is an *epidural needle system*. Sharing

certain structural features with an unrelated device having an unrelated function is insufficient to support a proper rejection on anticipation grounds.

The claims are not anticipated by Pyles U.S. Patent No. 5,669,882 within the proper meaning of 35 U.S.C. §102. This rejection should, therefore, be withdrawn.

The Examiner rejected claims 1, 4 through 6, and 9 through 11 under 35 U.S.C. §102(e) as being anticipated by Zohmann U.S. Patent No. 6,558,353. Applicant respectfully traverses this rejection for the following reasons.

The Examiner argues that Zohmann discloses a number of structural features set forth in Applicant's claimed invention. In order for a claim to be anticipated under 35 U.S.C. §102, a single prior art reference must disclose each and every element of the claimed invention. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984). If the reference fails to suggest even one limitation of the claimed invention, the claim is not anticipated. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. 409,411 (Fed. Cir. 1984).

The Examiner has failed to present a single prior art reference that anticipates Applicant's claimed invention. Specifically, the Examiner apparently ignored the claimed subject matter to assert that the claimed invention is anticipated by Zohmann. Applicant's claimed invention is a ***bone marrow biopsy device and system***. Applicant has amended claim 1 to clarify this point. Zohmann is an improved ***spinal needle***. Sharing certain structural features with an unrelated device having an unrelated function is insufficient to support a proper rejection on anticipation grounds.

The claims are not anticipated by Zohmann U.S. Patent No. 6,558,353 within the proper meaning of 35 U.S.C. §102. This rejection should, therefore, be withdrawn.

**Rejections under 35 U.S.C. §103:**

The Examiner rejected claims 12 and 14 under 35 U.S.C. §103(a) as being unpatentable over Lee U.S. Patent No. 4,314,565 in view of Yoon U.S. Patent No. 5,292,331. Applicant respectfully traverses this rejection for the following reasons.

The Examiner argues that Lee teaches the steps of inserting an aspiration device within an outer cannula to obtain a bone sample. The Examiner relies upon Yoon for a teaching of a “lumen terminating at a proximal opening and at a single laterally oriented distal opening immediately adjacent the distal tip. The Examiner concludes that one of ordinary skill in the art would have found the incorporation Yoon into the Lee device obvious in order to “facilitate precise penetration and positioning of the aspiration device while reducing tissue compression.”

The Lee discloses a bone biopsy system including an outer cannula, needles, and stylet. The distal tip configuration of Lee’s outer cannula and needles, upon closer inspection, do not contain the structure of the aspiration component of the instant invention. As a result, the advantages associated with Applicant’s invention are also missing from the Lee reference. Starting with the structure of the Lee distal end, the distal opening of the Lee outer cannula, and the needles for that matter, are both distally oriented and somewhat laterally oriented.

Applicant’s claimed invention specifies the difference of the distal portion of the aspiration component, i.e., the claims require that the lumen of the cannula body

terminates at a single laterally oriented “*distal opening immediately adjacent to the distal tip.*” This is in contrast to the distal opening of Lee, which is *at* the distal tip, or in other words, *is* the distal tip. The distal opening(s) described in Lee are *not* themselves immediately adjacent to the tip because they are open *at* the tip. Applicant further describes the structure of the distal tip in the independent claims to particularly point out this distinction.

Applicant’s claim language in combination with the specification and figures emphasize this important feature of the invention and its advantages. The claimed method of obtaining a bone marrow sample is a significant improvement over the method of Lee and other conventional methods as a result of the inventive aspiration device structure and function. That is, the claimed distal portion structure of the invention increases withdrawal of marrow tissue from the lateral region of the sampling site as compared to Lee or systems similar to Lee. The drawing in of marrow tissue located distal to the outer cannula tip, which have been compressibly/compacted and materially adulterated or altered by the bone penetration step, is reduced. Thus, an improved marrow sample having greater natural integrity than the prior art is obtained as a result of Applicant’s method.

Yoon does not provide the teachings that complement the shortcomings of Lee enough to support obviousness, and the Examiner has applied an inappropriate level of hindsight to fill a substantive gap in the Yoon disclosure and context. At the onset, Yoon is directed to a safety needle that contains an outer needle and a *spring biased* safety probe. Yoon in the paragraph bridging columns 2 and 3, and column 10, lines 58 through 63, recites a variety of tissue types in which the device can be used. There is no teaching

or fair suggestion in Yoon that the device can be used with bone tissue. That is because the Yoon device is not structured for penetration into hard tissues such as bone.

Furthermore, the text of Yoon to which the Examiner refers, when viewed in its proper full context, described a method that differs from Applicant's claimed method. In Yoon, because the safety needle component and safety probe components are integrated into a single device and cannot be separated, the penetration and rotation steps of Yoon are both performed with the simultaneous presence of the needle and probe. Applicant's method set forth in independent claim 12 clearly has step a) in which the penetration is effected using the outer cannula *with a stylet positioned within, which is removed* after the cortex is penetrated. In step c), the *aspiration device is inserted* through the outer cannula. Applicant's aspiration device is *not spring biased, nor is Applicant's device structured to have a fixed, pre-determined extension beyond the outer cannula*.

Applicant's claimed steps cannot be performed with the Yoon device.

Even further, the Yoon device because of its inseparability of components, would not afford the ability to obtain a core sample separate from an aspired sample without commingling the tissue types. In contrast, Applicant's claimed method using the inventive device accomplishes this.

As to the combination of Yoon with Lee, it is not understood why one of ordinary skill in the art would perform a method incorporating features of a device that is not designed to be used with hard bone tissue, with a device that is (i.e., Lee). Even less understood by Applicant is how the combination would have lead one of ordinary skill to arrive at the claimed invention, as the combination of Yoon into Lee would suggest a permanently fixed aspiration component with a predetermined extension that could not be

withdrawn from an outer cannula.

In summary, Applicant's claimed method cannot be considered obvious in view of the Lee and Yoon references, since Lee and Yoon do not present a collection of teachings that would fairly teach or suggest Applicant's claimed method. The examiner has failed to present a prima facie case of obviousness using these references.

Given the above, the claims are not unpatentable over these references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

The Examiner rejected claims 1 through 3, 6 through 8 and 11 through 14 under 35 U.S.C. §103(a) as being unpatentable over Krueger et al. U.S. Patent No. 6,478,751 in view of Pyles U.S. Patent No. 5,669,882. Applicant respectfully traverses this rejection for the following reasons.

The introduction to the rejection contains Krueger et al. as the primary reference and Pyles as a secondary reference. During the arguments, however, the Examiner often refers to "Lee" as if it were cited as the primary reference. Applicant has assumed that the references to Lee are a mistake and has addressed the Examiner's arguments accordingly.

The Examiner argues that Krueger teaches the claimed invention except for the aspiration device distal tip configuration having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal most point of the distal opening. The Examiner relies upon Pyles for such a structure teaching. The Examiner concludes that one of ordinary skill in the art would have found the invention to be obvious since one would want to rotate the needle during use with a

decreased chance of cutting tissue of the patient.

Applicant's invention is an improvement of the system described in Applicant's own U.S. Patent No. 6,478,751. The Examiner observed correctly that the Krueger reference is absent the claimed aspiration device and curved distal tip. The aspiration component of the Krueger reference includes a blunt aspiration cannula tip surface and a proximally located aspiration opening relative to the tip.

As to Pyles, the Examiner apparently ignored the subject matter of the Pyles invention. Applicant's claimed invention is a *bone marrow biopsy device and system*, whereas Pyles is an *epidural needle system*.

It is not understood why one of ordinary skill in the art would have used an spinal epidural needle of Pyles together with the Krueger bone biopsy system. The Examiner's alleged motivation is flawed. Again, the Examiner relies upon Pyles concluding that one of ordinary skill in the art would have found the invention to be obvious since one would want to rotate the needle during use with a decreased chance of cutting tissue of the patient. This is a very odd view point to say the least, because it would be actually be extremely undesirable to rotate a spinal epidural needle, which is delicately and intimately inserted alongside the central nervous system. Furthermore, one of ordinary skill doing this epidural procedure would not be motivated to incorporate an epidural needle within a larger diameter outer cannula system and insert this into the region to apply anaesthesia to begin with. In any case, a spinal epidural needle is irrelevant to Applicant's claimed invention, and one of ordinary skill in the art would not have combined Pyles with the bone biopsy system of Krueger to arrive at the claimed invention.

In summary, the Examiner has failed to present a collection of teachings that would fairly teach or suggest Applicant's invention. The Examiner has, thus, failed to present a prima facie case of obviousness.

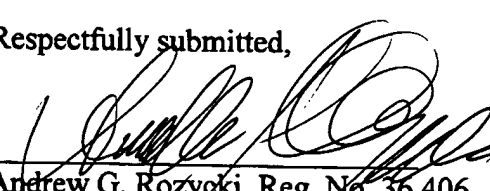
Given the above teachings, the claims are not unpatentable over these references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

**Conclusion:**

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

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Respectfully submitted,

  
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